FDA Approves Tagrisso for First-Line Lung Cancer Treatment

Osimertinib led to improved progression-free survival in people with common EGFR mutations.

April 19, 2018 By Food and Drug Administration (FDA)

On April 18, 2018, the Food and Drug Administration approved osimertinib (Tagrisso, AstraZeneca Pharmaceuticals LP) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Approval was based on a multicenter, international, randomized, double-blind, active-controlled trial (FLAURA, NCT02296125) conducted in 556 patients with EGFR exon 19 deletion or exon 21 L858R mutation-positive, unresectable or metastatic NSCLC who had not received previous systemic treatment for advanced disease. Patients were randomized (1:1) to receive osimertinib 80 mg orally once daily or "standard-of-care (SOC)" treatment of gefitinib 250 mg or erlotinib 150 mg orally once daily. Of those randomized to SOC, 20% received osimertinib as the next line of antineoplastic therapy.

The estimated median progression-free survival (PFS) was 18.9 months (95% CI: 15.2, 21.4) in the osimertinib arm and 10.2 months (95% CI: 9.6, 11.1) in the SOC arm (hazard ratio 0.46 (95% CI: 0.37, 0.57), $p<0.0001$). The confirmed overall response rate was 77% for the osimertinib arm and 69% for the SOC arm. The estimated median response durations for the osimertinib and SOC arms were 17.6 and 9.6 months, respectively. At the time of the primary PFS analysis, there were too few deaths to estimate or compare survival outcomes.

The most common adverse reactions (occurring in at least 20% of patients treated with osimertinib) were diarrhea, rash, dry skin, nail toxicity, stomatitis, and decreased appetite. Serious adverse reactions were reported in 4% of patients treated with osimertinib. The most common serious adverse reactions (≥1%) were pneumonia (2.9%), ILD/pneumonitis (2.1%), and pulmonary embolism (1.8%).

The recommended dose of osimertinib is 80 mg orally once daily, with or without food.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208065s008lbl.pdf.

FDA granted this application Priority review and Breakthrough designation. A description of FDA

expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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